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SECTION 2 - 510(k) SUMMARY

Small Size Orthocord® Suture

FEB 2 6 2013

Submitter's Name and Address	DePuy Mitek *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767
Contact Person	Tatyana Korsunsky Regulatory Affairs Specialist DePuy Mitek, Inc. *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767, USA Telephone: 508-828-3122 Facsimile: 508-977-6911 e-mail: tkorsuns@its.jnj.com
Name of Medical Device	Proprietary Name: ORTHOCORD® Classification Name: Suture, surgical, absorbable, polydioxanone; Suture, nonabsorbable, synthetic, polyethylene Common Name: Suture
Substantial Equivalence Facility	The Small Size Orthocord® Suture is substantially equivalent to: ▪ K040004: Orthocord® Suture (USP Size 2, Violet) (April 13, 2004) ▪ K043298: Orthocord® Suture (USP Size 2, Blue) (Dec 10, 2004) ▪ K071257: Minilok Anchor with #2-0 Orthocord® Suture (Jun 29, 2007) ▪ K080352: Microfix Anchor with #3-0 and 4-0 Orthocord® Suture (Mar 12, 2008) ▪ K946173: Ethibond Suture (January 09, 1995) ▪ K022715: Vicryl Suture (December 19, 2002) ▪ K122374, K071622, K041553: Fiberwire FiberLoop Suture (September 25, 2012; July 03, 2007; December 10, 2004)
Device Classification	Class II: • Sec. 878.4840 Absorbable polydioxanone surgical suture, product code NEW; • Sec. 878.5000 Nonabsorbable poly(ethylene terephthalate) surgical suture, product code GAT.
Device Description	Orthocord® Suture is a synthetic, sterile, braided, composite suture composed of dyed (D&C Violet #2 or D&C Blue #6) absorbable polydioxanone (PDS) and un-dyed non-absorbable polyethylene. The partially absorbable suture is coated with a copolymer of 90% caprolactone and 10% glycolide.

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	Small Size Orthocord Suture Sizes and Configurations: Size 0 Orthocord Suture; (single armed) Size 2-0 Orthocord Suture; (single armed) Size 3-0 Orthocord Suture; (single armed) Size 4-0 Orthocord Suture; (single armed) Size 4-0 Orthocord Suture in a Loop (both ends of suture swaged to one needle)
Indications for Use	ORTHOCORD Suture is indicated for use in general soft tissue approximation, and/or ligation, including orthopaedic procedures.
Safety and Performance	The determination of substantial equivalence for this device was based on a detailed device description, and conformance to consensus and voluntary standards. Non-clinical laboratory testing was performed demonstrating that the device conformed to the USP monograph for absorbable sutures, except for oversized diameter. The proposed Small Size Orthocord sutures are comprised of the same materials and are similar design to the predicate Size 2 Orthocord suture (K040004/K043298) with differences in size and braid construction. The proposed device, Small Size Orthocord, is currently offered in an anchor configuration of the DePuy Mitek's Minilok (K071257) and Microfix (K080352) anchors. Based on the indications for use, technological characteristics, and comparison to predicate devices, the ORTHOCORD suture has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

DePuy Mitek Incorporated.,
A Johnson and Johnson Company
% Ms. Tatyana Korsunsky
Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts, 02767

Letter dated: February 26, 2013

Re: K123668
Trade/Device Name: Small Size ORTHOCORD® Suture
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: Class II
Product Code: NEW, GAT
Dated: January 24, 2013
Received: January 28, 2013

Dear Ms. Korsunsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123668

Device Name: Small Size ORTHOCORD® Suture

Indications for Use:

The **Small Size ORTHOCORD® Suture** is indicated for:

ORTHOCORD Suture is indicated for use in general soft tissue approximation, and/or ligation, including orthopaedic procedures.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123668